REMARKS

Applicants respectfully request consideration of the application in view of the foregoing amendments and the following remarks.

Claim 1 is amended herein to limit the subject matter of the claimed invention to a nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof fused to a subunit B of heat labile enterotoxin of *E. coli* (LTB). Claim 8 is amended herein to correct the dependency, as necessitated by the cancellation of claim 7. Claim 10 is amended herein in accordance with the amendment to claim 1. Specifically, claim 10 is now limited to SEQ ID NOs 9, 11, 12, and 14, which are related to nucleic acid molecules encoding CEA-LTB fusions. Support for these amendments can be found, *inter alia*, in the original claims. No new matter has been added.

Claims 7, 22-24, 27-30, and 32-34 are canceled herein without prejudice to pursuing the subject matter of said claim in a later filed divisional application. Claims 3, 6, 9, 17-19, 25-26, 31, and 35 were canceled in a previous amendment.

Response to Restriction Requirement

The Office Action states that restriction to one of the following inventions is required under 35 U.S.C. §§ 121 and 372:

- Group I, Claims 1-2, 4-5, 7-8, 10-13, drawn to a nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the fusion protein is capable of producing an immune response in a mammal.
- Group II, Claims 14-16 and 20, drawn to a vector comprising the nucleic acid molecule of claim 13.
- Group III, Claim 21, drawn to a process for expressing a CEA fusion protein in a recombinant host cell.
- Group IV, Claims 22-23, drawn to a purified CEA fusion protein encoded by the nucleic acid molecule of claim 1.
- Group V, Claims 24, 27-28, drawn to a method of preventing or treating cancer comprising administering to a mammal a vaccine vector comprising the nucleic acid molecule of claim 1.

- Group VI, claims 29-30, drawn to an adenovirus vaccine vector comprising a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, and a promoter operably linked to the polynucleotide.
- Group VII, claim 32, drawn to a vaccine plasmid comprising a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, and a promoter operably linked to the polynucleotide.
- Group VIII, claims 33-34, A method of treating a mammal suffering from or predisposed to a CEA-associated cancer comprising introducing into the mammal a first vector comprising: a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, and a promoter operably linked to the polynucleotide; allowing a predetermined amount of time to pass; and introducing into the mammal a second vector comprising: a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, and a promoter operably linked to the polynucleotide.

The Office Action further states that Applicant is required to elect a single one of these inventions to which the claims must be restricted.

By way of this response, Applicants respectfully traverse the Lack of Unity of Invention/Restriction Requirement set forth above. However, in order to be fully responsive, Applicants provisionally elect Group I, claims 1-2, 4-5, 7-8, 10-13, drawn to a nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal. This election is being made without prejudice to the prosecution of the non-elected claims in a related patent application.

Applicants respectfully traverse the restriction of Groups I, II, and III because these groups of claims clearly share the same or special technical feature which contributes over the prior art. Under PCT Rule 13.1, inventions that are so linked as to form a single general inventive concept may be examined and prosecuted in a single case. As stated in the Office Action, if a group of claims share the same or corresponding special technical feature, one that identifies a contribution over the prior art, then those claims are so linked as to form a single general inventive concept.

Applicants respectfully assert that each of the claims in the referenced groups requires a nucleic acid molecule comprising a sequence of nucleotides encoding a CEA-LTB fusion protein, which is a special technical feature that is shared by the three groups. Group I contains claims (1-2, 4-5, 7-8, 10-13) to nucleic acid molecules comprising a sequence of nucleotides encoding CEA-LTB fusion proteins. Applicants note that by way of this amendment, subject matter directed to nucleic acid sequences encoding CEA fusions with DOM, FcIgG, CT, LTA has been canceled. Group II contains claims (14-16 and 20) to vectors comprising the nucleic acid molecules described in the Group I claims. Group III (claim 21) is drawn to a process of expressing a CEA-LTB fusion protein by a) introducing a vector comprising the nucleic acid molecule of claim 1 into a suitable host cell and (b) culturing the host cell under conditions which allow expression of said human CEA fusion protein.

Prior to the present invention, nucleic acid molecules encoding the CEA-LTB fusion proteins required by the claims were not known in the art, as evidenced by the PCT International Preliminary Report on Patentability ("IPRP," attached). Specifically, the IPRP states:

> The present application meets the criteria of Article 33(1) PCT with regard to invention 5 (CEA-LTB fusion) since the prior art neither teaches nor suggests the preparation and use of CEA-LTB fusion proteins for producing an immune response in a mammal.

See IPRP, last page, paragraph numbered 5. Moreover, because the same novel and inventive special technical feature is present in each of these claims, it would require no additional USPTO resources or present a burden on the USPTO to examine the claims of Groups I - III in a single application. Thus, all claims in Groups I, II, and III share a special technical feature that provides a contribution over the prior art. Accordingly Applicants respectfully submit that it is not proper to restrict the claims of these Groups into separate applications based on PCT Rule 13.2.

The conclusion of the Office that Group II and Group I cannot be examined in a single group is based, in part, on the reasoning that the invention of Group II does not require that the fusion protein is capable of producing an immune response in a mammal, as in Group I. See Office Action at page 3, last paragraph. Applicants respectfully note that all of the Group II claims are dependent on claim 13, which is indirectly dependent on claim 1. Thus, all of the features of claim 1 are required in the Group II claims.

Further, the conclusion of the Office that the process claim of Group III (claim 21) and the product claims of Group I cannot be examined in a single group is based, in part, on the reasoning that the composition defined by the invention of the Group I claims cannot be used in the method defined by claim 21 (Group III). See Office Action at page 5, 1st full paragraph. Applicants respectfully note that claim 21 is drawn to expression of the nucleic acid molecule of claim 1 in a host cell; thus, the composition of claim 1 is used in the method of claim 21.

In the event that the method of Group III is not rejoined with the composition claims of Group I following this response, Applicants request that the Group III claim is rejoined upon indication of allowable subject matter with regard to Group I. Applicants submit that since process claim 21 requires all of the limitations of claim 1, rejoinder is proper.

Applicants, therefore, respectfully submit that Groups I, II, and III should properly be examined in a single group in accordance with PCT Rule 13.2. As such, reconsideration and withdrawal of the requirement for restriction and/or regrouping of the claims, e.g., by combining Groups I- III respectfully requested.

Election of Species

The Office Action also states that the present application contains claims directed to more than one patentably distinct species of the generic invention. Specifically, The Office Action states that the application contains claims directed to the following patentably distinct species:

- Claims 1, 27-19, 32, 33 and dependent claims contain the following distinct species: DOM, FcIgG, CT, LTA, and LTB.
- Claim 2 and its dependent claims contain the following distinct species: human CEA protein or variant thereof or rhesus monkey CEA protein or variant thereof.
- Claim 10 and its dependent claims contain the following distinct species: SEQ ID NO: 7, 9, 11, 12, 14, 21, 25, 49, 50, and 52.
- Claims 16, 30 and dependent claims contain the following distinct species: Ad5, Ad6, or Ad24.
- Claim 23 and dependent claims contain the following distinct species: SEQ ID NO: 8, 10, 13, 15, 45, 46, 51, and 53.

The Office Action further states that Applicant is required under 35 U.S.C. § 121 to elect a single species for prosecution on the merits to which the claims will be restricted if no generic claim is finally held to be allowable.

By way of this response, Applicants designate the species of CEA-LTB for examination on the merits with regard to claim 1. Applicants note that the subject matter of claim 1 has been restricted to CEA-LTB by the amendment to claim 1 requested herein. Applicants further note that all pending claims are dependent on claim 1, either directly or indirectly. As such, all pending claims read on the elected species.

Applicants also designate nucleotide sequences encoding CEA-LTB fusion proteins comprising human CEA protein or a variant thereof for examination on the merits with regard to claim 2. All Group I claims read on the elected species. This election of species is being made with the understanding that the election requirement will be withdrawn upon making a determination that an allowable generic claim exists.

With regard to claim 10, Applicants designate SEQ ID NO:12 for examination on the merits. All Group I claims read on the elected species. This election of species is being made with the understanding that the election requirement will be withdrawn upon making a determination that an allowable generic claim exists.

With regard to claim 16, Applicants designate the species of Ad6. This election is being made in the event Group II claims are rejoined with the claims of Group I. All Group II claims read on the elected species. This election of species is being made with the understanding that the election requirement will be withdrawn upon making a determination that an allowable generic claim exists.

Summary

Applicants assert all claims are in condition for allowance and a favorable action on the merits is earnestly solicited.

If the Examiner believes that a telephone conference would be of value, she is requested to call the undersigned attorney at the number listed below.

Respectfully submitted,

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